



UNITED STATES PATENT AND TRADEMARK OFFICE

mw

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/404,010 | 09/23/1999 | YING LUO | A-68294/DJB/ | 7948 |
| 20350 | 7590 | 03/24/2004 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | ANDRES, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------|-------------------------------|----------------------------|--|
| Advisory Action | Application No. 09/404,010 | Applicant(s) LUO ET AL. | |
| | Examiner Janet L. Andres | Art Unit 1646 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 23 February 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

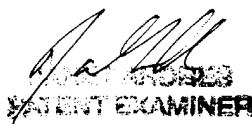
Claim(s) rejected: 25 and 27-33.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that Applicant has asserted a specific utility for diagnosis and prognostic determination of cancer. Applicant argues that this is a specific utility. Applicant argues that the specific biological activity is the detection of mutations of Mkinase associated with cancer and that this is disclosed in the specification. Applicant further argues that the specification discloses a determination of a difference in Mkinase nucleic acid gene levels as being indicative of cancer. Applicant argues that the specification also asserts the use of Mkinase nucleic acids for mapping specific chromosomal regions and for genetic analysis. Applicant argues that a reasonable correlation is supported because the application demonstrates interaction between Mkinase and Traf4.

Applicant's arguments have been fully considered but have not been found to be persuasive. What is provided on pp. 40-41 are general statements that "cell cycle associated disorders include cancer, that it "appears" that the protein is involved in the cell cycle, and that a difference in levels is "indicative of a disease state or a propensity for a disease state". These teachings are not sufficient to provide a substantial, real-world, and reasonably confirmed utility. There is no guidance to indicate that the nucleic acid is mutated or differentially expressed in any condition, including cancer. What is provided on p. 21 is similarly not sufficient to endow the nucleic acid with a utility. There are no genetic disorders identified which the polynucleotide could be used to identify. Applicant has identified no mutations of Mkinase, associated with cancer or not. That Mkinase "interacts" with Traf4 does not indicate that it is altered or differentially expressed in any cancer state or that it is diagnostic or prognostic of any cancer state. There are no teachings in the specification that would the artisan to diagnose any cancer or obtain any prognostic information, or to identify any other conditions based on genetic analysis. What is provided is merely an idea for an invention and an invitation to experiment to implement the invention, not the invention itself .


PATENT EXAMINER